

### **REMARKS**

Applicant has carefully reviewed and considered the Office Action mailed on June 24, 2003, and the references cited therewith. Applicant respectfully requests reconsideration and withdrawal of the rejections in view of the above amendments and the following remarks.

Claims 1-120 are canceled, and claims 121-196 are added; as a result, claims 121-196 are now pending in this application.

For the Examiner's convenience, it is noted that the new claims shown above are method claims based on original claim 106, which is now reflected in claim 121. Claim 121 also incorporates all the elements of original claim 1. Each of claims 122-194 depends either directly or indirectly upon claim 121.

No new matter has been added by way of the amendments herein.

### **Double Patenting Rejection**

Claim 60 was rejected to under 37 CFR 1.175 as being a substantial duplicate of claim 3.

Claims 91 and 92 were objected to under 37 CFR 1.175 as being a substantial duplicate of claims 76 and 75.

Claims 3 and 60 are cancelled, and claim 124 has been added. Also, claims 75-76 and 91-92 are cancelled and claims 173 and 174 have been added. In light of the cancellations and the appropriately added new claims, the Examiner's rejection has been obviated and Applicant respectfully requests withdrawal of the rejection.

### **§112 Rejection of the Claims**

Claims 53 and 80 were rejected under 35 USC § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 53 is cancelled and claim 162 has been added. The trademark/trade names recited in claim 53 are not reproduced in claim 162, thus claim 162 contains no indefinite terms. Claim 80 is cancelled and claim 178 has been added. Claim 178 properly refers to claim 177, which contains proper antecedent basis for the term "filler". As a result, the claims are in condition for allowance, and withdrawal of the rejections is respectfully requested.

**§102 Rejection of the Claims**

Claims 1, 6-8, 26, 27, 32 and 35 were rejected under 35 USC § 102(b) as being allegedly anticipated by Katz et al. (U.S. 5,028,435). This rejection is respectfully traversed. To constitute anticipation all material elements must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). On page 10 of the Office Action, lines 3-6, the Examiner stated that the Katz '435 patent discloses a transdermal patch. The patch disclosed by Katz is useful for therapeutic applications (col. 11, lines 36-39), such as treating malaria, microbial infections, and high fever (col. 5, line 46). Applicant's invention recites a patch that is used to improve the appearance of wrinkles (in the specification, page 2, lines 27-28). Applicant's invention is not a transdermal patch, but is a cosmetic patch that treats the skin. The Katz '435 patent does not disclose or suggest using a patch to improve the appearance of wrinkles. The Katz '435 patent does not anticipate all material elements of Applicant's invention, therefore the rejection has been obviated. Applicant respectfully requests withdrawal of the Examiner's rejection.

Claims 1, 6-9, 15-16, 24, 26-27, 32, 39-40, 44-45, 49-50, 72-73, 79, 85-86, 88-89, 97-98, 100-101, 106-107, 112-113, and 115-116 were rejected under 35 USC § 102(b) as being allegedly anticipated by Porter et al. (U.S. 5,785,978). This rejection is respectfully traversed. To constitute anticipation all material elements must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). On page 10 of the Office Action, last paragraph, the Examiner stated that the Porter '978 patent discloses "a pressure sensitive adhesive patch with a flexible backing". The backing of Porter, however, is an impermeable backing (col. 4, lines 37-39; and col. 12, lines 21-22, claim 1). Applicant's invention discloses a backing that is "porous and/or vapor permeable" (in the specification, page 8, lines 18-20; page 8, line 28 to page 9, line 1; and page 10, line 24 to page 11, line 3). The permeable nature of the backing is important in reducing the incidence of skin irritation found in known patches (in the specification, page 8, lines 18-22). For the Examiner's convenience, it is noted that the term "permeable" has been incorporated into claims 121, 195, and 196. Porter does not anticipate all material elements of Applicant's invention. Therefore, Porter does not anticipate claims 121-196, and withdrawal of the Examiner's rejection is respectfully requested.

Claims 1, 3, 35, 39-40, 44-45, 49-51 and 58-60 were rejected under 35 USC § 102(b) as being allegedly anticipated by Chiang et al. (U.S. 5,242,334). This rejection is respectfully traversed. To constitute anticipation all material elements must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). On page 11 of the Office Action, line 6, the Examiner stated that the Chiang '334 patent discloses a transdermal device comprising permeation enhancers. The Chiang '334 patent, however, does not disclose a device comprising permeation enhancers, but actually teaches away from their use. For example, see col. 4, lines 3-5, wherein the Chiang '334 patent states "[a] key element of this invention is the use of a matrix which permits high delivery rates for drugs without the use of added skin penetration rate enhancers" (emphasis added). Applicant's invention discloses a patch that includes a skin absorption enhancer (in the specification, page 37, lines 20-24). The Chiang '334 patent therefore does not anticipate all material elements of Applicant's invention. Applicant respectfully requests withdrawal of the Examiner's rejection.

Claims 1, 3, 58-60, and 82-83 were rejected under 35 USC § 102(b) as being allegedly anticipated by Sharma et al. (U.S. 5,229,130). This rejection is respectfully traversed. To constitute anticipation all material elements must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). On page 11 of the Office Action, lines 14-15, the Examiner stated that the Sharma '130 patent discloses a transdermal pressure sensitive adhesive. The adhesive disclosed by the Sharma '130 patent is useful for treating infections, pain, and anorexia nervosa (col. 4, lines 13-14). Applicant's invention discloses a patch that is used to improve the appearance of wrinkles (in the specification, page 2, lines 27-28). The Sharma '130 patent does not disclose or suggest using a patch to improve the appearance of wrinkles. The Sharma '130 patent therefore does not anticipate all material elements of Applicant's invention. Applicant respectfully requests withdrawal of the Examiner's rejection.

Claims 1, 7-9, 41-42, 58-60, and 85-86 were rejected under 35 USC § 102(b) as being allegedly anticipated by Cilento et al. (U.S. 5,059,189). This rejection is respectfully traversed. To constitute anticipation all material elements must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A. 1978). On pages 11-12 of the Office Action, the Examiner states that the Cilento '189 patent discloses an adhesive patch. The dressing disclosed by the Cilento '189 patent is useful for treating inflammation (col. 6, lines 26-27), viruses and

acne (col. 6, lines 36-37). Applicant's invention discloses a patch that is used to improve the appearance of wrinkles (in the specification, page 2, lines 27-28). The Cilento '189 patent does not disclose or suggest using a patch to improve the appearance of wrinkles. The Cilento '189 patent therefore does not anticipate all material elements of Applicant's invention. Applicant respectfully requests withdrawal of the Examiner's rejection.

### **§103 Rejection of the Claims**

The following rejections by the Examiner are outlined on pages 12-20 of the Office Action. Claims 21-23, 29, 31, 36-38, 46-48, 62, 74, 81, 84, 90, 99, 108, 109-111, 114 and 117 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Porter et al. (U.S. 5,785,978). Claims 21-23, 31, 43 and 56-59 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Cilento et al. in view of Berry et al. (U.S. 4,784,857). Claims 36-38 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Chiang et al. (U.S. 5,242,334). Claims 51-53, 75-81, and 91-93 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Porter et al. in view of Smith et al. (U.S. 5,460,620), in further view of Crotty et al. (U.S. 6,106,857) and Mitra et al. (U.S. 5,890,486). Claims 94-96 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Porter et al. in view of Torgerson et al. (U.S. 5,730,966). These rejections are respectfully traversed.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988) and *In re Piasecki*, 745 F.2d at 1472, 223 U.S.P.Q. at 788. If the Examiner does not establish a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness. M.P.E.P. § 2142. To establish a *prima facie* case of obviousness, three criteria must be met.

First, the reference (or references) relied upon must teach or suggest all the limitations of the claims. See *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art.").

Second, the reference (or references) relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that

would have motivated the skilled artisan to modify a reference or to combine references. See *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986).

Third, the proposed modification of the reference (or references) relied upon must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. In other words, a hindsight analysis is not allowed. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); *In re Erlich*, 3 U.S.P.Q.2d 1011, 1016 (Bd. Pat. App. & Int. 1986).

Claims 21-23, 29, 31, 36-38, 46-48, 62, 74, 81, 84, 90, 99, 108, 109-111, 114 and 117

On page 12 of the Office Action, the Examiner states that claims 21-23, 29, 31, 36-38, 46-48, 62, 74, 81, 84, 90, 99, 108, 109-111, 114 and 117 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Porter et al. (U.S.P. 5,785,978). Porter, however, does not teach or suggest all of the limitations of Applicant's claims. As discussed above, Porter et al. disclose a patch with an impermeable backing (col. 4, lines 37-39; and col. 12, lines 21-22, claim 1). Applicant's invention discloses a backing that is "porous and/or vapor permeable" (in the specification, page 8, lines 18-20; page 8, line 28 to page 9, line 1; and page 10, line 24 to page 11, line 3). The permeable nature of the backing is important in reducing the incidence of skin irritation found in know patches (in the specification, page 8, lines 18-22). The reference, therefore, does not teach or suggest all the claim elements of Applicant's invention. Applicant respectfully requests withdrawal of the rejection.

Claims 21-23, 31, 43 and 56-59

On page 14 of the Office Action, the Examiner states that claims 21-23, 31, 43 and 56-59 are rejected under 35 USC § 103(a) as being allegedly unpatentable over Cilento et al. in view of Berry et al. (U.S. 4,784,857). Even in combination, however, Cilento and Berry do not teach or suggest all of the limitations of Applicant's claims. The Cilento '189 patent discloses an adhesive patch. The dressing disclosed by the Cilento '189 patent is useful for treating inflammation (col. 6, lines 26-27), viruses and acne (col. 6, lines 36-37). The Berry '857 patent discloses a devise that may be used to deliver nitroglycerin, oxybutynin, or phenazocine

transdermally (Abstract). Applicant's invention discloses a patch that is used to improve the appearance of wrinkles (in the specification, page 2, lines 27-28). Neither the Cilento '189 patent nor the Berry '857 patent discloses or suggests using a patch to improve the appearance of wrinkles. Thus, the Cilento '189 and the Berry '857 patents, alone or in combination, do not teach or suggest all the claim elements of Applicant's invention. Applicant respectfully requests withdrawal of the Examiner's rejection.

#### Claims 36-38

On page 16 of the Office Action, the Examiner states that claims 36-38 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Chiang et al. (U.S. 5,242,334). Chiang, however, does not teach or suggest all of the limitations of Applicant's claims. Applicant's invention recites a patch that includes a skin absorption enhancer. The Chiang '334 patent does not disclose a device comprising permeation enhancers and actually teaches away from their use. For example, see col. 4, lines 3-5, wherein the Chiang '334 patent states "[a] key element of this invention is the use of a matrix which permits high delivery rates for drugs without the use of added skin penetration rate enhancers" (emphasis added). The Chiang '334 patent therefore does not teach or suggest all the elements of Applicant's invention. Applicant respectfully requests withdrawal of the Examiner's rejection.

#### Claims 51-53, 75-81, and 91-93

On page 17 of the Office Action, the Examiner states that claims 51-53, 75-81, and 91-93 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Porter et al. (U.S. 5,785,978) in view of Smith et al. (U.S. 5,460,620), in further view of Crotty et al. (U.S. 6,106,857) and Mitra et al. (U.S. 5,890,486).

With regard to claims 51-53 (now reflected in claims 160-162), on page 17 of the Office Action, last paragraph, the Examiner states that Smith suggests the inclusion of fragrances into a device and that the Crotty '857 patent discloses a device that comprises fragrances. The Examiner states that it "would have been obvious to a skilled artisan to include a fragrance into the composition in order to provide a pleasant masking effect for the cosmetic agent." To establish a *prima facie* case of obviousness, the Examiner must show that some objective

teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The suggestion to combine must come from the prior art itself and not Applicant's specification or impermissible hindsight. The Porter, Smith, and Crotty patents do not teach or suggest the combination disclosed by Applicant's invention. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. With no suggestion to combine in the prior art, the Examiner's rejection cannot stand.

With regard to claims 77-78 (now reflected in claims 175-176), on page 17 of the Office Action, lines 8-13, the Examiner discusses that Porter lacks a disclosure of a keratolytic agent. Smith discloses resorcinol as a keratolytic agent. The Examiner presumes a skilled artisan "would have been motivated to include the keratolytic agent of Smith into Porter in order to improve the health of the applied skin." To establish a *prima facie* case of obviousness, the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The suggestion to combine must come from the prior art itself and not Applicant's specification or impermissible hindsight. Neither the Porter '978 patent nor the Smith '620 patent contain such an objective teaching or suggestion. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Furthermore, there is no teaching or suggestion of a reasonable expectation of success of the combination in the prior art. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). Absent a teaching for the reasonable expectation of success, the Examiner has not met the initial burden of factually supporting a *prima facie* conclusion of obviousness.

On page 18 of the Office Action, first paragraph, the Examiner states that Smith “in combination with Porter discloses the general combination of resorcinol with an adhesive patch.” To establish a *prima facie* case of obviousness, the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Neither cited reference contains an objective teaching that would suggest the combination stated by the Examiner. As such, a *prima facie* case of obviousness has not been made, and the rejection cannot stand.

With regard to claims 79-81 (now reflected in claims 177-179), on page 18 of the Office Action, third paragraph, the Examiner suggests combining the Smith reference with the disclosure of the Mitra ‘486 patent’s disclosure of malto dextrin. To establish a *prima facie* case of obviousness, the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Neither cited reference contains an objective teaching that would suggest the combination stated by the Examiner. As such, a *prima facie* case of obviousness has not been made, and the rejection cannot stand.

#### Claims 94-96

On page 19 of the Office Action, the Examiner states that claims 94-96 were rejected under 35 USC § 103(a) as being allegedly unpatentable over Porter et al. (U.S. 5,785,978) in view of Torgerson et al. (U.S. 5,730,966). As discussed above, the Porter ‘978 patent does not teach or suggest all of the limitations of Applicant’s claims. The Porter ‘978 patent discloses a patch with an impermeable backing (col. 4, lines 37-39; and col. 12, lines 21-22, claim 1). The Torgerson ‘966 patent discloses thermoplastic elastomeric copolymers and compositions for topical application (Abstract). The Torgerson ‘966 patent does not disclose a patch with a permeable backing. Applicant’s invention discloses a patch comprising backing that is “porous and/or vapor permeable” (in the specification, page 8, lines 18-20; page 8, line 28 to page 9, line 1; and page 10, line 24 to page 11, line 3). The permeable nature of the backing is important in reducing the incidence of skin irritation found in known patches (in the specification, page 8, lines



18-22). The Porter '978 and the Torgerson '966 patents, alone or in combination, do not teach or suggest all the claim elements of Applicant's invention. Applicant respectfully requests withdrawal of the rejection.

Allowance of claims 121-196 is earnestly requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) 359-3261) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743


Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O.Box 1450, Alexandria, VA 22313-1450, on this 23 day of December, 2003.

**Candis B. Buending**

Name

Signature

